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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,283	11/13/2001	Carl-Axel Bauer	06275-150003	5064

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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,283	BAUER ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 11-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on March 4, 2004 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 9 and 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record in view of (Cazzola et al(U) of record and Andersson et al. (U.S.Patent No. 6598603B1)) and further in view of Giardina et al. (U.S.Patent No. 6,277,862B1).

Carling et al. on the abstract, page 4, lines 23-29, page 7-9(examples), and page 10 (claims), teach a medicament containing effective amounts of formoterol and

budesonide in combination for simultaneous, sequential or separate administration by inhalation in treatment of respiratory disorder with effective amounts within Applicants' range set forth in claim 9. Carling et al. teach that the combination comprising formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but the combination also has a rapid onset of action and this new feature is of utmost importance in order to establish a higher compliance for patients and it provides a rescue medicine thereby avoiding the necessity for the patient of carrying two different inhalers. (page 4, lines 4-10). Carling et al. teach that the combination of formoterol and budesonide in a single formulation simplifies life for patients considerably and makes life more comfortable and secure in treating respiratory disorder. (page 4, lines 10-12, lines 23-29).

Carling et al. do not expressly teach the treatment of COPD.

Cazzola et al. on the abstract teaches that formoterol is effective in patients with COPD.

Anderson et al. teach budesonide is useful treating COPD as well as asthma. (column 4, lines 18-24).

Giardina et al. report that COPD and asthma are respiratory diseases. (column 1, lines 37-40, column 5, lines 55-57, claim 47).

It would have been obvious to skilled artisan to employ the Carling's medicament in treatment of COPD since COPD is well known respiratory disease as disclosed by Giardina et al. Further, each of active agents (budesonide and formoterol) utilized in Carling's medicament are individually known to treat COPD conditions as well. One of

ordinary skilled in the art would have been motivated to employ Carling's medicament in treatment of COPD with reasonable expectation of success since each of the active agents utilized in Carling's medicament are well known individually for treating respiratory disease, COPD. Absent any evidence to contrary, there would have been a reasonable expectation of successfully treating COPD by employing Carling's formulation to achieve greater efficiency and duration of action with a rapid onset of action and to simplify life for COPD patients by making life more comfortable and secure in treating respiratory disease (e.g. COPD).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed on March 4, 2004 have been fully considered but they are not persuasive. Applicants argue that Carling et al. states that his combination of formoterol and budesonide is suitable for treating "asthma and other respiratory disorder"; the only specific respiratory disorder mentioned is asthma and as explained in the Declaration of Jan Trofast, the recitation of Carling et al. of "other respiratory

disorders" as meant by Carling and his co inventors (one of whom was Dr. Trofast) to include only other respiratory disorders similar to asthma. This is not persuasive because COPD and asthma are well known by Giardina et al. as respiratory disorders and that both of active agents (formoterol and budesonide) are known to be effective in treating COPD. The Declaration of Jan Trofast has been carefully reviewed but it is examiner's position that at the time the invention was made, the treatment of COPD employing Carling's formulation is obvious since COPD is well known respiratory disorder among with asthma by Giardina et al. and the active agents contained in Carling's formulation is effective individually for the treatment of COPD regardless of whether the COPD and asthma are very different diseases and that may require very different treatment protocols as stated in the Declaration. In instant Application, the active agents contained in Carlings' formulation are effective for the treatment of COPD, well-known respiratory disorder. It is examiner's position that the active agents utilized in Carling are effective individually for the treatment of COPD which is well-known respiratory disorder among with asthma therefore, it would have been obvious to treat COPD with Carling's formulation for the convenience thereby avoiding the necessity for the patient of carrying two different inhalers for the dual treatment of COPD. Applicants next argue that Barnes et al. states that COPD is quite different from the variable airway obstruction and symptoms in asthma, which rarely progress in severity. This is not persuasive because regardless of the symptoms and characteristics of asthma and COPD which may be different, it is noted that formoterol and budesonide are individually effective for the treatment of COPD and COPD is well known respiratory

disorder. Applicants next argue that Buist report that corticosteroids are ineffective against the primarily neutrophilic inflammation seen in COPD. This is not persuasive because the Carling's formulation employs specific corticosteroid, namely, budesonide. The specific corticosteroid, budesonide is effective for the treatment of both COPD and asthma as taught by Andersson et al. (column 4, lines 18-25). Applicants next argue that the phrase "other respiratory disorders' broadly, as urged by the examiner, it would follow that the artisan would have considered the Carling et al. combination suitable for the treatment of respiratory disorders such as lung cancer and asbestosis. This is not persuasive because COPD as asthma are well known respiratory disorders by Giardina et al. and that Carling's formulation comprises the active agents that are individually effective for the treatment of COPD. Therefore, one of ordinary skill in the art would have been motivated to employ the formulation taught by Carling for the treatment of COPD with a reasonable expectation of successfully treating COPD since each of the active agents are known to treat respiratory disorder namely, COPD. Applicants argue that Rabe states that for asymptomatic COPD patients should be not treated with drug and this expresses doubt regarding the appropriateness of combining long-acting B2 agonists and corticosteroids for the treatment of COPD. This is not persuasive because Carling formulation comprises specific corticoid steroid (i.e. budesonide) and specific long-acting B2 agonist (i.e. formoterol) which are both individually known to be effective in treating COPD and that it would have been obvious to one of ordinary skill in the art to employ symptomatic COPD patients with Carlings to achieve rapid on set of action

for treating symptomatic COPD. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Nederland Tijdschrift Voor Geneeskunde of record and Saunders Manual of Medical Practice are withdrawn as references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
June 10, 2004